

### CLAIMS

1. *In vitro* serological diagnosis method in which, in a sample to be tested, the presence is detected of antibodies specific to an infectious microbial agent,  
5 characterized in that it is controlled that said sample to be tested contains a human serum by detecting whether human immunoglobulins react with an antigen containing protein A from a *Staphylococcus aureus* bacterium.
2. Serological diagnosis method as in claim 1, characterized in that :
  - the sample to be tested is caused to react with a first antigen ( $Ag_1$ )  
10 containing protein A, preferably all or part of a *Staphylococcus aureus* bacterium containing protein A, and
  - the presence is detected of an antigen-antibody reaction product ( $Ag_1-Ac_1$ ) in which the antibody ( $Ac_1$ ) is a human immunoglobulin, by causing said reaction product ( $Ag_1-Ac_1$ ) to react with a detection substance which is a substance  
15 reacting with a human immunoglobulin and not reacting with said first antigen ( $Ag_1$ ).
3. Serological diagnosis method as in claim 1 or 2, characterized in that the following steps are performed, in which:
  - a) on a solid substrate are deposited said first antigen containing protein A  
20 ( $Ag_1$ ), and at least one second antigen ( $Ag_2$ ) which is characteristic of a microbial infectious agent ( $Ag_2$ ), and
  - b) the said first antigen ( $Ag_1$ ) and second ( $Ag_2$ ) antigen(s) are caused to react with a sample to be tested, and
  - c) it is detected whether a human immunoglobulin ( $Ac_1$ ) reacts with said  
25 first antigen ( $Ag_1$ ) by causing the reaction product ( $Ag_1-Ac_1$ ) to react with a secondary detection antibody ( $Ac_2$ ) which is a labelled anti-human immunoglobulin which does not react with protein A.
4. Serological diagnosis method as in any of claims 1 to 3, characterized in that said first antigen is a whole *Staphylococcus aureus* bacterium containing  
30 protein A.
5. Serological diagnosis method as in any of claims 1 to 4, characterized in that the presence is detected of a said reaction product ( $Ag_1-Ac_1$ ) with an anti-

human immunoglobulin ( $Ac_2$ ) which is an immunoglobulin of animal origin, preferably goat or chick immunoglobulin.

6. Serological diagnosis method as in any of claims 1 to 5, characterized in that the presence is detected of a reaction product of said first antigen ( $Ag_1$ ) with a human immunoglobulin ( $Ac_1$ ) using a substance labelled by fluorescent marking, in particular an anti-human immunoglobulin labelled with fluorescein.

7. Serological diagnosis method as in claim 6, characterized in that:

- a series of tests is performed at increasing dilutions of the sample to be tested and the detection substance ( $Ac_2$ ) is applied which is an immunoglobulin conjugated with a fluorescent substance, and

- it is verified whether a reaction product ( $Ag_1-Ac_1-Ac_2$ ) can be detected by fluorescence at a dilution of the sample to be tested of 1/200 or less.

8. Serological diagnosis method as in any of claims 1 to 7, characterized in that said infectious microbial agent consisting of said second antigen is chosen from among micro-organisms containing a bacterium, a virus, a parasite or a fungus.

9. Serological diagnosis method as in claim 8, characterized in that said second antigen ( $Ag_2$ ) is an intracellular bacterium or a virus.

10. Serological diagnosis method as in claim 8 or 9, characterized in that said second antigen is chosen from among bacteria of the genus *Rickettsia*, *Coxiella*, *Bartonella*, *Tropheryma*, *Ehrlichia*, *Chlamydia*, *Mycoplasma*, *Treponema*, *Borrelia*, and *Leptospira*.

11. Serological diagnosis method as in claim 10, characterized in that said second antigen corresponding to the infectious microbial agent is a bacterium responsible for endocarditis.

12. Serological diagnosis method as in either of claims 9 to 10, characterized in that said second antigen corresponding to said infectious microbial agent is a viral antigen chosen from among the H.I.V., C.M.V. or Epstein-Barr viruses.

13. Diagnosis kit which can be used to implement the method as in any of claims 1 to 12, characterized in that it includes at least one positive control controlling inclusion of a human serum in the sample to be tested comprising a said first antigen containing protein A ( $Ag_1$ ) and reagents enabling the detection of

the presence of a reaction product of said first antigen with a human immunoglobulin ( $Ac_1$ ).

14. Diagnosis kit as in claim 13 , characterized in that it includes :

5 - a solid substrate on which a said first protein A-containing antigen has been deposited ( $Ag_1$ ) and a said second antigen corresponding to an infectious microbial agent ( $Ag_2$ ) to be detected, and

- a detection substance ( $Ac_1$ ) to detect a reaction product of said first antigen with a human immunoglobulin containing a labelled anti-human immunoglobulin which is a goat or chick immunoglobulin labelled with fluorescent  
10 marking.